

### **Remarks**

Claims 1, 3-7, 9-11, 13-14, 16, and 18-19 are pending. Claims 1 and 11 are the independent claims.

### **Claim Amendments**

Claims 1 and 11 have been amended to incorporate the subject matter of claims 2 and 12, respectively. Specifically, claims 1 and 11 now recite that an anatomically adapted contact surface is formed on an outer side of the two base parts, the anatomically adapted contact surface being adapted to a surface contour of a bone in which the prosthesis is to be implanted. Support for these amendments may be found for example at paragraphs [0025]-[0026] of the specification.

Claims 2 and 12 have been canceled.

No new matter has been introduced by the foregoing amendments.

### **Rejections Under 35 U.S.C. § 103**

Claims 1-7, 9, 11-14, 16 and 18 are rejected under 35 U.S.C. § 103(a) as being obvious over U.S. Patent No. 6,440,168 to Cauthen ("Cauthen") in view of U.S. Patent No. 6,368,350 to Erickson et al. ("Erickson"). Claims 10 and 19 are rejected as being obvious over Cauthen in view of Erickson, and further in view of U.S. Patent No. 5,899,941 to Nishijima et al. ("Nishijima"). The rejections are respectfully traversed.

Cauthen, alone or in combination with the secondary references, does not teach or suggest a parts assembly for a prosthesis as claimed by Applicant. Cauthen describes a spinal implant that includes two hemicylindrical or hemielliptical elements that each engage one of an

adjacent pair of vertebrae. (Abstract; Col. 3, Lines 3-5). The implant includes an internal ball and socket arrangement that allows articulation of the elements, and fusion chambers and openings thereto in the outer walls that facilitate bone ingrowth. (Col. 5, Line 63 – Col. 6, Line 4; Col. 7, Lines 39-48). Cauthen does not teach or suggest a parts assembly for a prosthesis including two base parts having an anatomically adapted contact surface formed on a respective outer surface of the two base parts, the anatomically adapted contact surface being adapted to a surface contour of a bone in which the prosthesis is to be implanted, as claimed by Applicant.

The implants of Cauthen are generally cylindrical or elliptical in overall shape. (Col. 7, Lines 30-34; Col. 7 Line 65 – Col. 8, Line 2). Cauthen discloses that the outer walls of the implant can also be provided with threads to secure the implant in position. (Col. 7, Lines 48-52). Nowhere does Cauthen suggest that the outer surface of the elements may be anatomically adapted to the surface contour of the bone in which the prosthesis is to be implanted. Rather, Cauthen teaches that vertebral sections should be removed by “drilling or chipping a generally circular bore having a diameter and depth adapted to generally match the implant.” (Col. 10, Lines 26-30). Thus, Cauthen describes adapting the patient’s vertebrae to accommodate the cylindrical or elliptical implants. This teaching is in direct contrast to Applicant’s claimed invention, which includes a contact surface that is anatomically adapted to the surface contour of the vertebral bones in which the prosthesis is to be implanted.

Applicant’s invention advantageously allows implantation of the parts assembly as a prosthesis in the skeleton in such a way that the prosthesis is integrated in the skeleton in a natural manner. (Para. [0012]). The anatomically adapted contact surface helps the prosthesis to integrate into the skeleton with a precise fit in the individual patient. (Para. [0012]). Slipping of

the prosthesis is prevented by means of the anatomically adapted contact surface. (Para. [0012]). Moreover, the arrangement of the bone on the anatomically adapted contact surface when the prosthesis is implanted counteracts any undesirable rotation of the prosthesis relative to the bones, which are adjacent to the prosthesis, so that stable support of the prosthesis is promoted. (Para. [0013]). Furthermore, the anatomically adapted surfaces decrease the amount of material required to be removed from the bone during implantation and increases the ease of implantation of the implant. (Para. [0014]). Cauthen teaches away from Applicant's implant design by teaching a one-shape-fits-all cylindrical/elliptical implant having continuous threads over the implant surface to "help secure the implant in position once implanted." (Col. 7, Lines 48-52).

Furthermore, as acknowledged by the Examiner, Cauthen does not teach a prosthesis in which the base parts and coupling parts are made of the same material, selected from the following group: polyetherketone (PEK), polyetheretherketone (PEEK), polyacryl etherketone (PAEK), polyetherketoneketone (PEKK), polyetherketoneetherketoneketone (PEKEKK) and polyetherketoneetherketone (PEKEK), as claimed by Applicant in claims 1 and 11. The Examiner also acknowledges that Cauthen does not teach a device in which the contact surfaces have a material coating, as claimed by Applicant in claims 10 and 19. Accordingly, the Examiner cites secondary references Erickson and Nishijima as teaching these limitations, respectively. However, the secondary references do not remedy the deficiencies of Cauthen.

Erickson teaches an implant having three components: two contact surfaces and a third, separate component positioned between the contact surfaces. (Col. 4, Lines 52-60). Erickson does not teach or suggest that the device base and coupling part may be or should be associated or formed in one piece, as claimed by Applicant in claims 1 and 11, respectively. Nor does

Erickson suggest that all of the elements of the device should be formed from the same material selected from the following group: polyetherketone (PEK), polyetheretherketone (PEEK), polyacryletherketone (PAEK), polyetherketoneketone (PEKK), polyetherketoneetherketoneketone (PEKEKK) and polyetherketoneetherketone (PEKEK). Rather, Erickson teaches that the device elements may be manufactured from certain listed materials, while the articulating surfaces may be prepared from a separate list of materials. (Col. 5, Lines 49-65). Therefore, one of ordinary skill in the art, would not have been motivated to create devices in which a base part and coupling part are associated and made of the same material, as claimed by Applicant.

Nishijima teaches a metallic implant device having a polymeric coating on its sliding surfaces, a reverse configuration of the devices claimed by Applicant. (Col. 5, Lines 20-50). Nishijima indicates that this configuration of materials is desirable for mechanical strength, corrosion resistance, stability within the body, hardness, compression and deformation resistance, and wear. (Col. 5, lines 43-50). Accordingly, one of ordinary skill in the art would not have been motivated to combine the teachings of Nishijima, Erickson and Cauthen to derive Applicant's claimed invention, at least because Nishijima teaches that a device having the reverse construction of the claimed devices is desirable. Nishijima further teaches applying a hydroxyapatite coating to the metallic device surfaces. (Col. 5, Lines 28-35). Thus, one of ordinary skill in the art would not have had any reason to apply such a coating to polymeric device surfaces, as claimed by Applicant.

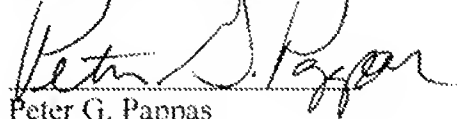
Overall, one of ordinary skill in the art would not have been motivated to derive Applicant's claimed invention based on Cauthen and the secondary references at least because

the combination is contrary to the teachings of these references. Specifically, to derive the claimed invention, one would have to disregard (i) Cauthen's teaching of a cylindrical/elliptical implant design, (ii) Erickson's teaching of a device having separate base and coupling parts that may be fabricated of different materials, and (iii) Nishijima's teaching of a metallic device having a polymeric coating. Accordingly, a *prima facie* case of obviousness has not been established based on the cited references. The rejections should therefore be withdrawn.

**Conclusion**

For the foregoing reasons, it is respectfully submitted that Applicant's claims are patentable over the prior art of record. Prompt allowance of each of pending claims 1, 3-7, 9-11, 13-14, 16, and 18-19 is therefore respectfully solicited. The undersigned kindly invites the Examiner to contact him by telephone if any outstanding issues can be resolved by conference or Examiner's amendment.

Respectfully submitted,

  
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